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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/078,649	02/19/2002	Yun Hwang Choe	213.1077-CTML-U	5287
22856	7590	10/25/2004	EXAMINER	
MUSERLIAN, LUCAS AND MERCANTI, LLP 475 PARK AVENUE SOUTH NEW YORK, NY 10016				CHANNAVAJJALA, LAKSHMI SARADA
		ART UNIT		PAPER NUMBER
		1615		

DATE MAILED: 10/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/078,649	CHOE ET AL.
<b>Examiner</b>	<b>Art Unit</b>	
	Lakshmi S Channavajjala	1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### **Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- THE MAILING DATE OF THIS COMMUNICATION**

  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1)  Responsive to communication(s) filed on 11 June 2004.

2a)  This action is **FINAL**.                            2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4)  Claim(s) 1-24 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5)  Claim(s) \_\_\_\_\_ is/are allowed.  
6)  Claim(s) 1-24 is/are rejected.  
7)  Claim(s) \_\_\_\_\_ is/are objected to.  
8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All    b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1)  Notice of References Cited (PTO-892)
  - 2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)
  - 3)  Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.

- 4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.

5)  Notice of Informal Patent Application (PTO-152)

6)  Other: \_\_\_\_\_.

## DETAILED ACTION

Receipt of terminal disclaimer and remarks dated 6-11-04 is acknowledged.

### *Response to Arguments*

Applicant's arguments with respect to claims 1-24 have been considered but are moot in view of the new ground(s) of rejection.

Upon reconsideration the following provisional double patenting rejection has been withdrawn:

Claims 1-24 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22 of copending Application No. 10/078,730. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant and co-pending claims recite a compound wherein one of the variables of D1 and D2 of the instant compound is OH. Accordingly, a compound resulting from instant D1 and D2=OH, is the same as the compound of co-pending applications.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The following new rejection is applied to the pending claims:

### *Claim Rejections - 35 USC § 103*

Claims 1-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greenwald et al.

Greenwald et al teaches drug delivery systems comprising polyethylene prodrugs of amino-containing compounds, the compounds being water-soluble. The prodrugs of Greenwald comprise PEG-spacer-linker-drug. Greenwald et al teaches the prodrugs for efficient and specific

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targeting of anti-tumor agents such as daunorubicin (page 476, col.10). Greenwald teaches that acylating agents used in the prodrugs act as bifunctional linkers (page 476, col.1). Further, Greenwald teaches several PEG triggers such as ester-based, carbonate-based or carbamate based triggers. With respect to the claimed compounds, while Greenwald does not teach exactly teach the instant formula, the compounds described by Greenwald in scheme 3, Table 1 and chart 1 read on the instant compounds. Further, Greenwald teaches preparation of compounds such as 4A and 4B (page 482) that are also encompassed by the claimed compounds. Accordingly, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to prepare instant pegylated prodrug compositions from the teachings of Greenwald because Greenwald also teaches preparing drug delivery compounds based on PEG as triggers and bind drug molecules such as anti-tumor compound, via bifunctional linkers. Further, Greenwald suggests that the compounds have high solubility and offer site specific targeting of drugs, in particular, anti-tumor drugs.

### ***Double Patenting***

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

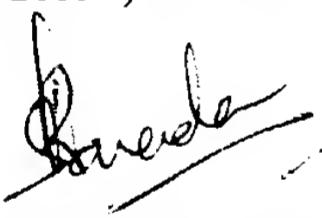
Claims 1-24 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-22 of copending Application No. 10/078,730. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

It is noted that instant claimed compound recites the variable "J", which could be NR. The co-pending application also claims compounds with the NR, at the same position as that of J in the instant compound. Further, the compounds of instant dependent claim 18 are the same as the compounds of claim 18 of co-pending application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 7.30 AM -4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lakshmi S Channavajjala  
Examiner  
Art Unit 1615  
October 22, 2004